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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------------------------|-------------|----------------------|-------------------------|------------------|
| 09/483,969 | 01/18/2000 | Brian E. Farley | VNUS-53427 | 9082 |
| 24201 | 7590 | 01/21/2005 | EXAMINER | |
| FULWIDER PATTON LEE & UTECHT, LLP | | | RODRIGUEZ, CRIS LOIREN | |
| HOWARD HUGHES CENTER | | | ART UNIT | PAPER NUMBER |
| 6060 CENTER DRIVE | | | 3763 | |
| TENTH FLOOR | | | | |
| LOS ANGELES, CA 90045 | | | DATE MAILED: 01/21/2005 | |

Please find below and/or attached an Office communication concerning this application or proceeding.

| | | | |
|------------------------------|------------------------|---------------------|--|
| Office Action Summary | Application No. | Applicant(s) | |
| | 09/483,969 | FARLEY ET AL. | |
| | Examiner | Art Unit | |
| | Cris L. Rodriguez | 3763 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).

'Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) Responsive to communication(s) filed on 9/13/04, and 11/12/04.

2a) This action is **FINAL**. 2b) This action is non-final.

3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4) Claim(s) 34-84 is/are pending in the application.

4a) Of the above claim(s) 35,37,44-47,51,54,56-59,62,64,67,69-71 and 82 is/are withdrawn from consideration.

5) Claim(s) 68 and 72-81 is/are allowed.

6) Claim(s) 34,36,38-40,43,48-50,52,53,55,61,65,66,83 and 84 is/are rejected.

7) Claim(s) 41 and 42 is/are objected to.

8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9) The specification is objected to by the Examiner.

10) The drawing(s) filed on 13 September 2004 is/are: a) accepted or b) objected to by the Examiner.

 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) All b) Some * c) None of:

- Certified copies of the priority documents have been received.
- Certified copies of the priority documents have been received in Application No. _____.
- Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

| | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____. | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Double Patenting

1. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

2. Claim 53 is rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1, 5, 10, and 12-14 of U.S. Patent No. 6,139,527. Although the conflicting claims are not identical, they are not patentably distinct from each other because both claims a catheter having extendable members, and electrodes located at the extendable members.

Election/Restrictions

3. Please note that claims 51, 67, and 82 have been withdrawn from consideration by the examiner as being drawn to a non-elected species of figure 8a.

4. Claim 68 is generic and allowable. Claims 75 and 76 are no longer withdrawn from consideration since all of the claims to this species depend from or otherwise include each of the limitations of an allowed generic claim. However, claims 69-71, and 82 remain withdrawn from consideration since they do not depend upon or otherwise include all the limitations of an allowed generic claim as required by 37 CFR 1.141.

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

6. Claims 34, 36, 38-40, 43, 48-50, 52, 53, 55, 60, 61, 65, 66, 83, and 84 are rejected under 35 U.S.C. 103(a) as being unpatentable over Fleischman (US 5,885,278) in view of Behl (US 5,709,224).

Fleischman discloses an ablation catheter and a method for applying energy. The ablation catheter, (figs 7-11A), has a working end 22, at least four exposed electrically conductive surfaces 20(1) located at the distal end of the catheter, and a plurality of electrically conductive lines (figs 10-11A) electrically connected to the exposed surfaces. Fleischman also discloses the ablation catheter having electrodes 34, and the electrodes having temperature sensors 68 to measure the temperature of the hollow anatomical structure (Col. 10, lines 10-25). The ablation catheter can be used in other regions of the body (col. 6 lines 20-25). In column 9 lines 25-32, Fleischman set forth that the electrodes could be in a bi-polar mode in which the ablation energy emitted by one electrode 28 is returned through another element on the spline leg 22 reading on the "pair of exposed surfaces of unlike polarity" of the claims. However, Fleischman is moot to cause preferential shrinkage.

Behl teaches that is known to use an ablation catheter having electrodes to apply energy and cause shrinkage of an anatomical structure, such as veins and other body

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lumens (col. 5 lines 17-27). The energy applied is between ranges 200kHz to 1.25MHz. This range falls between the ranges as applicants. Given the teachings it would have been obvious to one having ordinary skill in the art at the time the invention was made to use Behl's energy ranges with Fleischman's ablation catheter to cause preferential shrinkage of a vein, since Behl suggests that RF energy can be applied to a vein or other body lumens. Doing so would have shrunk the hollow anatomical structure, and monitor the site during the medical procedure.

Allowable Subject Matter

7. Claims 41, and 42 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.
8. Claims 68, and 72-81 allowable over the prior art of record.

Response to Arguments

9. Applicant's arguments filed September 13, 2004 have been fully considered but they are not fully persuasive.

10. A recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. In a claim drawn to a process of making, the intended use must result in a manipulative difference as compared to the prior art. See *In re Casey*, 152 USPQ 235 (CCPA 1967) and *In re Otto*, 136 USPQ 458, 459 (CCPA 1963).

11. Behl is being used to show an ablation device having the ranges disclosed by applicant. And if Behl were capable of performing preferential shrinkage of the vein within applicant's preferred frequency, then Fleischman's ablation device would be capable of performing preferential shrinkage in another environment within the frequency levels set forth.

12. In response to applicant's argument that Fleischman is directed to ablating myocardial tissue, and that Behl is directed to occluding blood vessels, the fact that applicant has recognized another advantage which would flow naturally from following the suggestion of the prior art cannot be the basis for patentability when the differences would otherwise be obvious. See *Ex parte Obiaya*, 227 USPQ 58, 60 (Bd. Pat. App. & Inter. 1985).

13. It is noted that the rationale to modify or combine the prior art does not have to be expressly stated in the prior art; the rationale to modify may be expressly or implied contained in the prior art or it may be reasoned from knowledge generally available to one of ordinary skill in the art, established scientific principles, or legal precedent established by prior case law. *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir 1988); *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992).

14. Motivation to combine the references may be found in nature of problem to be solved. (See *Ruiz v. A.B. Chance Co.*, 69 USPQ2d 1686 (CAFC 2004)).

15. While there must be some teaching, reason suggestion, or motivation that the references be combined to arrive at the claimed invention, there is no requirement that the references explicitly suggest the combination. *In re Nilssen*, 851, F2d 1401, 1403, 7

USPQ2d 1500, 1502 (Fed. Cir. 1988). The suggestion or motivation to combine the references or teachings can derive solely from the existence of a teaching, which one of ordinary skill in the art would be presumed to know, and the use of that teaching to solve the same or similar problem which it addresses. *In re Wood*, 599 F.2d 1032, 1037, 202 USPQ 171, 174 (CCPA 1979).

16. In response to applicant's argument that there is no suggestion to combine the references, the examiner recognizes that obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. See *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988) and *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992). In this case, the suggestion to combine the references is that both references are ablation catheters either one with different intended use. However, Behl teaches preferential shrinkage of the vein. Therefore, it would have been obvious to use Fleischman's catheter with Behl's energy ranges to cause preferential shrinkage of the vein.

17. In response to applicant's argument that the examiner's conclusion of obviousness is based upon improper hindsight reasoning, it must be recognized that any judgment on obviousness is in a sense necessarily a reconstruction based upon hindsight reasoning. But so long as it takes into account only knowledge which was within the level of ordinary skill at the time the claimed invention was made, and does not include knowledge gleaned only from the applicant's disclosure, such a

reconstruction is proper. See *In re McLaughlin*, 443 F.2d 1392, 170 USPQ 209 (CCPA 1971).

Conclusion

18. THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Cris L. Rodriguez whose telephone number is 571-272-4964. The examiner can normally be reached on 7:30 am - 4:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Nick Lucchesi can be reached on 571-272-4977. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

January 13, 2004


Cris L. Rodriguez
Examiner
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